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SIPDIS

SENSITIVE

DEPT FOR WHA/AND, EB/IPE SWILSON
COMMERCE FOR 4331/MAC/WH/MCAMERON
DOC FOR J. BOGER
USTR FOR B. WILSON, B. HARMAN

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SUBJECT: ELI LILLY STRUGGLING WITH PATENT PIRACY

1. (SBU) Summary. Eli Lilly, one of the ten pharmaceutical companies that hold patents in Peru, continues to combat the piracy of one of its best selling products, Zyprexa. According to Eli Lilly representatives, two local distributors, Ozone and PharmaIndustria, are selling copies of Zyprexa on the local market. One pirated version, sold by Ozone, is a slight modification of Lilly's molecule; the other version is structurally identical. Indecopi, Peru's IPR administrator, has yet to take action on these cases, claiming that Eli Lilly must prove that Ozone and Farma Industria are selling pirated copies of Zyprexa. Eli Lilly has lost over \$2.4 million in sales. We are investigating whether Indecopi's actions violate Article 28 of the TRIPS agreement, which states the rights of patent holders, and Article 34, which places the burden of proof on the alleged infringer. End Summary.

Two Copies of Zyprexa Available

2. (SBU) We met with Edgard Olaizola, General Manager of Eli Lilly Peru, on August 31 to discuss violations of intellectual property rights in the pharmaceutical arena. Olaizola informed us that Eli Lilly, which holds five pharmaceutical patents in Peru, is facing two patent violations. Both violations involve Eli Lilly's Zyprexa drug (olanzapine), which is Lilly's top selling product for schizophrenia and bipolar disorder. Lilly sells olanzapine worldwide and holds a patent for this product in countries where the product is sold. Eli Lilly also holds exclusivity rights for the formulation and several processes of olanzapine. Eli Lilly sells Zyprexa primarily to Peruvian government health institutions, including EsSalud and police and military hospitals.

3. (SBU) In January 2005, local distributor Ozone began selling a copy of Zyprexa, manufactured by Microlab in India. According to Eli Lilly lab analysis, the Ozone drug is a slight modification of olanzapine. In February, Indecopi, at Eli Lilly's request, issued a precautionary measure against Ozone based on the possible infringement of Lilly's process patent. The precautionary measure prohibited Ozone from selling the product. Indecopi, however, lifted the precautionary measure on May 31, several weeks before the GOP launched its annual procurement bid for medications.

4. (SBU) In June 2005, Farma Industria, one of Peru's largest pharmaceutical companies and producers of generic drugs, introduced another copy of Zyprexa to the market. Cipla, also based in India, manufactures this copy of Zyprexa. Although Farma Industria claims that it sells a different form of olanzapine, Eli Lilly studies show that the drug is in fact an exact copy of Lilly's patented olanzapine.

Indecopi Fails to Act

5. (SBU) Eli Lilly officials met several times with Indecopi officials, who have yet to take any action. Nestor Escovero, Director of Indecopi's patent office, informed Eli Lilly that the company needed to prove that the new drugs were pirated copies. According to Olaizola, Indecopi's patent office staff work closely with Peruvian pharmaceutical distributors, advising them on generic drug production. One patent examiner, claims Olaizola, is now the head of Ozone's regulatory department. Olaizola asserts that Indecopi tends to favor local distributors over foreign companies and doubts that it will do anything to stop the sale of pirated drugs. (Note and Comment: Indecopi is also targeting other multinationals. In a recent unannounced visit to the Swissotel, now an American company, Indecopi officials demanded to see all software licenses. Officials were disappointed when the hotel produced the necessary documents. This is an example of Indecopi's lack of understanding and deliberate targeting of foreign companies. It also underscores the cost of doing business in Peru. End

Note and Comment.)

16. (SBU) Eli Lilly, as a result of Indecopi's inaction and the lifting of the precautionary measure in June, has lost market share and estimates damages at \$2.4 million in lost sales. The GOP held eight procurement bids totaling \$300,000 each for pharmaceutical supplies to EsSalud and military/police hospitals in June-August; Eli Lilly won none of these bids, despite holding previous contracts with the GOP. Instead, Ozone and Farma Industria earned GOP contracts. Eli Lilly appealed the procurement process.

Possible Violation of TRIPS?

17. (SBU) Despite Eli Lilly's claims that both Ozone and Farma Industria are selling pirated copies of Zyprexa, Indecopi has placed the burden of proof on Eli Lilly instead of the Peruvian companies. Article 28 of the WTO TRIPS Agreement grants certain rights to patent holders. Article 34 clearly states that in cases of copyright infringement, the burden of proof should be placed on the alleged infringer, not the patent holder. Indecopi's failure to fully investigate Eli Lilly's claims may be a direct violation of Peru's obligations under the TRIPS agreement.

Comment

18. (SBU) Eli Lilly is not the first pharmaceutical company to face patent problems in Peru. Although the GOP is a member of the WTO, signatory to the TRIPS agreement and is in the process of negotiating a Free Trade Agreement with the United States, government officials do not always act in accordance with international regulations. We will arrange a conference call with Eli Lilly and the Department of Commerce to discuss the facts of this case and the possible TRIPS violations. We will also bring this case to the attention of the Peruvian FTA negotiators, stressing the importance of upholding intellectual property rights, particularly during negotiations.

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